

Appl. No. 10/730,276

Remarks/Arguments

Since the shortened statutory period for reply has expired, a petition for a one-month extension of time and the fee therefor is submitted herewith.

The claims have been amended to more clearly reflect the invention. Specifically, claims 6 and 7 have been amended, and no new claims have been added. Even in light of these amendments, no new matter has been added. It would be appreciated if the Examiner would indicate the acceptance of this amendment in the next office communication.

The Examiner has rejected claims 1-10 under 35 U.S.C. § 103(a) as being unpatentable over Nicolais (EP 0 982 236) in view of Hamilton et al. (EP 0 737 481) in view of Ahlqvist (US 5, 881,534). However, the Examiner has not met her burden of establishing a prima facie case of obviousness because the combined teachings of the Nicolais, Hamilton, and Ahlqvist references do not teach or suggest every claim limitation of claim 1 and those claims depending therefrom. Thus, withdrawal of this rejection is respectfully requested.

Appl. No. 10/730,276

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference or combination of prior art references, must teach or suggest all the claim limitations.

In this case, the combined teachings of the Nicolais, Hamilton, and Ahlqvist references do not teach or suggest every claim limitation, namely "establishing an inert gaseous atmosphere in the envelope." As stated in a previous response, an important aspect of the present invention is a process for packaging a polyethylene prosthetic implant that yields a package which guarantees that the ambient air, particularly the oxygen that it contains, cannot come into contact with the implant, *even if the tightness of the sachet is compromised*. To provide such a package, the process of the present invention involves first placing a polyethylene implant in a flexible sachet and then creating a vacuum in the sachet. Then, the process recites putting the sachet containing the implant in an envelope and *establishing an inert gaseous atmosphere in the envelope*. In

Appl. No. 10/730,276

contrast, since the prior art is concerned with providing sterile packaging for polyethylene implants by utilizing an inert environment *surrounding the implant*, the prior art does not teach the present invention.

As the Examiner pointed out, Nicolais teaches a process for packaging sterilizable materials . According to the Nicolais process, a product is first placed in a container under vacuum. Then, the container containing the product is placed in an outer container. However, Nicolais is silent with respect to forming an inert gaseous atmosphere within the envelope, as set forth in the Office Action.

Further, as the Examiner also pointed out, Ahlqvist teaches a process for sterilizing an article made from polymeric material by radiation. The Ahlqvist process involves enclosing an article in a gas permeable package with an oxygen absorber to create an inert environment *directly surrounding the article*. However, Ahlqvist is silent with respect to forming an inert environment *outside* the package containing the article to be sterilized.

As set forth in Ahlqvist, a primary object of that process is to reduce the secondary processes appearing in polymeric

Appl. No. 10/730,276

material during and after sterilizing dosages of γ -irradiation due to the presence of oxygen. To achieve the objective of mitigating the negative effects caused by oxygen during sterilization, the Ahlqvist patent teaches placing oxygen absorbers in the package with the article to be sterilized to create an inert environment *surrounding the article*. The Ahlqvist process could not achieve such an objective if an inert environment was created outside the packaging containing the article. Thus, Ahlqvist is silent with respect to forming an inert gaseous atmosphere *outside* the package containing the article to be sterilized.

Since the Nicolais and the Ahlqvist references both lack a teaching of establishing an inert atmosphere within an envelope surrounding a sachet containing a prosthetic implant, as required by at least claim 1, the combination of these references does not disclose every claim limitation. Further, assuming *arguendo* that there is motivation to combine the teachings of these references, the combination would still not teach the process of the present invention. At best, the process resulting from the combined prior art references would first place an article in a first container with an oxygen scavenger to create an inert environment directly surrounding the article in the first container, as

Appl. No. 10/730,276

disclosed in Ahlqvist, then put the first container housing the article in a second container, and heat seal the second container, as taught by Nicolais. Since the combination of the teachings of the Nicolais and Ahlqvist patents do not teach "establishing an inert gaseous atmosphere in the envelope" surround the sachet, as required by claim 1, withdrawal of the rejection to this claim and those depending therefrom is respectfully submitted.

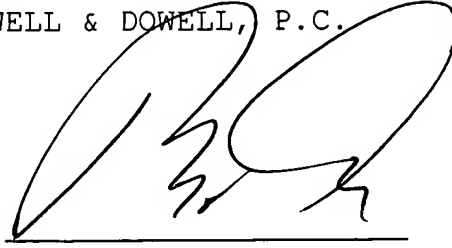
In view of the foregoing, reconsideration of the 35 U.S.C. § 103(a) rejection is respectfully requested and favorable consideration and allowance of the claims solicited. Further, no new claims have been added, and the amendments to the claims do not impart any new matter. Thus, the listing of claims submitted herein do not raise new issues that would require additional consideration or searching. Should the Examiner have any questions regarding this response, the amendments submitted herewith, or the allowability of the claims, it would be appreciated if the Examiner would contact the undersigned attorney of record at the telephone number provided below for purposes of facilitating prosecution of this application and for scheduling an interview, if necessary.

Appl. No. 10/730,276

Respectfully submitted,

DOWELL & DOWELL, P.C.

By

A large, stylized handwritten signature in black ink, appearing to be 'R. Dowell', written over a horizontal line.

Ralph A. Dowell, Reg. No. 26,868

Date: August 24th ~~25th~~, 2006

DOWELL & DOWELL, P.C.

Suite 406, 2111 Eisenhower Ave.

Alexandria, VA 22314

Telephone - 703 415-2555

Facsimile - 703 415-2559

E-mail - dowell@dowellpc.com